BECKMAN COULTER CE

AU

Instructions For Use

CO2 BICARBONATE

REF OSR6190 4 x 25 mL R1
OSR6290 4 x 50 mL R1

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

System reagent for the quantitative determination of bicarbonate in human serum and plasma on Beckman Coulter analysers.

SUMMARY AND EXPLANATION

Bicarbonate measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance. The determination of bicarbonate (HCO_3^-) is used in conjunction with other clinical and laboratory information for the evaluation of acid-base status. An elevation of the HCO_3^- level may be observed in compensated respiratory acidosis and metabolic alkalosis. Low HCO_3^- levels may be observed in compensated respiratory alkalosis and metabolic acidosis.[1] Additional laboratory determinations will permit differentiation between metabolic and respiratory conditions.

METHODOLOGY

The Bicarbonate reagent utilizes an enzymatic method to measure bicarbonate in human serum and plasma. In this procedure bicarbonate (HCO_3^-) and phosphoenolpyruvate (PEP) are converted to oxaloacetate and phosphate in the reaction catalyzed by phosphoenolpyruvate carboxylase (PEPC). Malate dehydrogenase (MD) catalyzes the reduction of oxaloacetate to malate with the concomitant oxidation of a reduced nicotinamide adenine dinucleotide (NADH). This oxidation of the NADH results in a decrease in absorbance of the reaction mixture measured bichromatically at 380/410 nm proportional to the HCO_3^- content of the sample.

CHEMICAL REACTION SCHEME

$$PEP + HCO_3^- \xrightarrow{PEPC} Oxaloacetate + H_2PO_4^-$$

$$Oxaloacetate + NADH + H^+ \xrightarrow[Magnesium]{MD} Malate + NAD^+$$

SPECIMEN

TYPE OF SPECIMEN

Serum and heparinised plasma samples free from haemolysis are the recommended specimens. Separate serum or plasma from cells promptly to minimise haemolysis.

Once separated from cells, HCO_3^- in serum is stable for several hours when stored at 2...8°C and protected from exposure to air.[2]

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

MD (microbial)	> 2,000 U/L
PEPC (microbial)	> 572 U/L
NADH	1.6 mmol/L
PEP	8.2 mmol/L
Magnesium	2.8 mmol/L
Also contains preservatives.	

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

REAGENT PREPARATION

The reagent is ready for use and can be placed directly on board the instrument.

STORAGE AND STABILITY

The reagent is stable unopened, up to the stated expiry date when stored at 2…8°C. Once open, reagent stored on board the instrument is stable for 7 days.

CALIBRATION

CALIBRATOR REQUIRED

Bicarbonate Calibrator Cat No. ODC0019.

The calibrator bicarbonate value is traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 351.

Recalibrate the assay every day, or when the following occur:

Change in reagent lot number or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced.

Absorption of atmospheric CO_2 by the reagent on board the analyzer can impair calibration stability. This effect will vary depending upon the rate of use. Consequently each laboratory should set a calibration frequency in the instrument parameters appropriate to their usage pattern.

QUALITY CONTROL

Control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement. The paediatric application is suitable for use with small volume serum/plasma samples.

CALCULATIONS

The Beckman Coulter analysers automatically compute the bicarbonate concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference[3,4]	
Adult	21 − 31 mmol/L
Newborn	17 − 24 mmol/L
Infant	19 − 24 mmol/L
2 months − 2 years	16 − 24 mmol/L

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

INTERFERENCES

Interfering Substances[5]

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

AU600/AU640

Lipemia:	Interference less than 5% up to 1,000 mg/dL Intralipid.
Haemolysis:	Interference less than 10% up to 500 mg/dL haemoglobin
Icterus:	Interference less than 5% up to 40 mg/dL billirubin

Refer to Young[6] for further information on interfering substances.

PERFORMANCE CHARACTERISTICS

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Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

LIMITATIONS

Visible signs of a crystalline precipitate which settles out upon storage may be evident in the reagent bottle. Reagent with crystalline precipitate may be used without affecting results. However, if any trends or sudden shifts in control values are detected, which are not corrected by recalibration then an alternative vial of reagent should be used.

LINEARITY

The test is linear within a concentration range of 2.0 to 45.0 mmol/L.

SENSITIVITY

The lowest detectable level on an AU640 analyser was estimated at 0.71 mmol/L.

The lowest detectable level represents the lowest measurable level of bicarbonate that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

METHODS COMPARISON

Patient samples were used to compare this Bicarbonate Reagent OSR6190 on an AU640 to a blood gas analyzer method.

y = 0.999x – 1.207	r = 0.98	n = 102	Sample range = 9.4 – 32.2 mmol/L

PRECISION

The following data was obtained[7] on an AU640 using 3 serum pools analysed over 20 days.

n = 80	Within-run		Total	
Mean mmol/L	**SD**	**CV%**	**SD**	**CV%**
9.0	0.37	4.15	0.63	7.02
25.1	0.29	1.15	0.58	2.31
34.9	0.37	1.05	0.71	2.02

ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
CO21N	Bicarbonate (Serum)
CO21NP	Bicarbonate (Serum Paediatric)

Setting Sheet Footnotes
User defined
† Bicarbonate Calibrator Catalogue Number ODC0019
* Values set for working in mmol/L

‡ Depends on usage pattern in the laboratory.

REVISION HISTORY

Added new languages

Preceding version revision history

IFU updated to add Ukrainian language

REFERENCES

1. Tietz, N.W., Hg., Fundamentals of Clinical Chemistry, 3rd edition, W.B. Saunders Company, 1999.
2. WHO/DIL/LAB/99.1 Rev.2; Use of anticoagulants in diagnostic laboratory investigations, 2002.
3. Kaplan, L.A. and Pesce, A.J. Clinical Chemistry Theory, Analysis, Corelation 3rd Edition, CV Mosbey, 1996.
4. Painter PC, Cope JY, Smith JL. Reference information for the clinical laboratory. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia:WB Saunders Company, 1999;1803pp.
5. NCCLS, Interference Testing in Clinical Chemistry EP7-P, 1986.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests, AACC, 5th ed. AACC Press, 2000.
7. NCCLS, Evaluation Protocol EP5-A, 1999.

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